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 Counterclaimants Kyphon Sàrl and
 Medtronic, Inc.

UNITED STATES DISTRICT COURT
 CENTRAL DISTRICT OF CALIFORNIA

PABBAN DEVELOPMENT, INC.,

Plaintiff,

vs.

KYPHON SÀRL, MEDTRONIC, INC.,
 AND DOES 1-100,

Defendants.

KYPHON SÀRL and MEDTRONIC,
 INC.,

Counterclaimants,

vs.

PABBAN DEVELOPMENT, INC., BIO-
 MEDICAL DEVICES, INC., BIO-
 MEDICAL DEVICES
 INTERNATIONAL, INC., and HARRY
 N. HERBERT,

Counterdefendants.

No.: SACV 10-533 CJC (RNBx)

**DEFENDANTS KYPHON SÀRL
 AND MEDTRONIC, INC.'S
 AMENDED COUNTERCLAIM AND
 DEMAND FOR JURY TRIAL**

Honorable Cormac J. Carney

1 Pursuant to Federal Rule of Civil Procedure 15(a)(1), Defendants
2 Kyphon Sàrl (“Kyphon”) and Medtronic, Inc. (“Medtronic”) amend their counterclaim
3 as follows:
4

5 1. Pabban Development, Inc. (“Pabban”) is a California corporation with its
6 principal place of business in Irvine, California.
7

8 2. Bio-Medical Devices, Inc. (“BMD”) is a California corporation with its
9 principal place of business in Irvine, California.
10

11 3. Bio-Medical Devices International, Inc. (“BMDI”) is a California
12 corporation with its principal place of business in Irvine, California.
13

14 4. Pabban, BMD and BMDI are affiliated companies.
15

16 5. Harry N. Herbert (“Herbert”) is the Chief Executive Officer of Pabban
17 and is responsible for the day-to-day operations of Pabban, BMD and BMDI.
18

19 6. Herbert, directly or indirectly, owns a controlling interest in Pabban,
20 BMD and BMDI.
21

22 7. Kyphon is in the business of selling products used in the treatment of
23 spinal fractures. In appropriate circumstances, such fractures may be treated by
24 injecting bone cement into the vertebra in the spine and filling the cavity. The cement
25 reinforces the walls of the vertebra, which prevents compression. The medical device
26 used to inject the cement into the vertebra is known as a “bone filler device.”
27
28

1 8. Medtronic is the global leader in medical technology – alleviating pain,
2 restoring health and extending life for millions of people around the world.

3
4 9. In late 2007, Kyphon was in the very early stages of developing an
5 improved “bone filler device.” However, Kyphon expected that this potential new
6 offering would not be market-ready until at least May 2009 – significantly after it
7 anticipated its competition would offer similar devices for sale. If those competitors
8 beat Kyphon to the market, they would obtain a “first to market” advantage. The
9 “first to market” advantage can be critical in the medical device industry because even
10 a several month head start can significantly damage a competitor’s potential market
11 share. Based in part on the fact that its potential new offering would not be “market-
12 ready” until May 2009 and its competitors were farther along in the development
13 process, Kyphon was interested in purchasing a market-ready product to avoid losing
14 critical market share.

15
16 10. At the same time, Kyphon was considering whether to develop a new
17 “bone filler device.” BMD, BMDI and Pabban had developed such a device, which
18 was called the Natrix Bone Cement Delivery System (“Natrix System”). BMD and
19 BMDI owned the tooling for the Natrix System, Pabban owned the assets related to
20 the product, and Syntech International, Inc., manufactured the product. Kyphon
21 became aware of the “Natrix System” and communicated to Pabban and Herbert an
22 interest in learning more about it to determine if Kyphon should continue to develop
23 its own product or purchase the market-ready “Natrix System.”

24
25 11. As a part of Kyphon’s initial discussions with Herbert, he represented to
26 Kyphon that the Natrix System had four principal advantages over Kyphon’s existing
27 “bone filler device.”
28

- 1 • First, the Natrix System reduced radiation exposure for physicians using
- 2 the device;
- 3
- 4 • Second, the Natrix System generated pressure of over 1500 psi, which
- 5 allowed it to deliver much preferred higher viscosity cement than that
- 6 delivered through other injection systems on the market;
- 7
- 8 • Third, the Natrix System could be operated with one hand, which was of
- 9 interest to physicians; and
- 10
- 11 • Fourth, unlike any other product on the market, a physician using the
- 12 Natrix System could instantly halt cement flow.
- 13

14 12. In November 2007, Kyphon met with Pabban, BMD, BMDI, and Herbert
 15 at BMD and BMDI's facility. At that meeting, Pabban, BMD and BMDI not only
 16 demonstrated the Natrix System, but Herbert represented that the product had been
 17 used successfully in 30-40 live procedures, and had been through at least eight rounds
 18 of marketing trials. Representatives of Kyphon, including Kyphon's CEO, Bob
 19 White, told Herbert if Kyphon purchased the Natrix System, it intended to launch the
 20 Natrix System at the prestigious and very important North American Spine Society
 21 ("NASS") conference in October 2008. Herbert, on behalf of Pabban, BMD and
 22 BMDI, repeatedly assured Kyphon that the Natrix System was ready for market.

23

24 13. In addition to representing to Kyphon that the Natrix System was ready
 25 for market, Pabban, BMD, BMDI, and Herbert represented to Kyphon that:

- 26
- 27 • If BMD and BMDI did not sell Natrix to Kyphon, BMD and
- 28 BMDI would start selling the product itself "within 30-45 days."

- 1 • BMD and BMDI planned to release Natrix “by end of March
- 2 [2008].”
- 3
- 4 • As BMD and BMDI moved forward “with our marketing trials and
- 5 production processes to our April 2 [2008] market release, we
- 6 continue to validate the NATRIX market capabilities.”
- 7
- 8 • Natrix is an “Immediately Accretive class one device, production-
- 9 ready.”
- 10

11 14. After these initial meetings, Kyphon conducted an “on-site” due
12 diligence session at BMD and BMDI’s facility on May 22-23, 2008. Kyphon
13 conducted a second (and final) on-site due diligence session on June 12, 2008.

14
15 15. On August 7, 2008, Kyphon and Pabban entered into an Asset Purchase
16 Agreement (“APA”).

17
18 16. Prior to closing of the APA, Kyphon requested permission to test the
19 Natrix System in its own facilities. Pabban refused Kyphon’s request because of
20 purported concerns with confidentiality. It turns out, however, that Pabban refused to
21 provide Kyphon with access to the Natrix System for testing because such testing may
22 have revealed the product was defective and not market-ready.

23
24 17. After the APA closed, Kyphon learned that the Natrix System was
25 unmerchantable and defective at the time Kyphon purchased it from Pabban. The
26 device uses a hydraulic delivery system to push bone cement through the delivery
27 tube. Saline fluid resides in a polyurethane bag inside the handle of the device. In
28 August 2008, after the APA closed, Kyphon received its first shipments of Natrix

1 devices manufactured by Syntech International, Inc. (“Syntech”). Kyphon thereafter
2 discovered fluid inside the packaging, which suggested the devices were leaking
3 saline. After conducting an investigation, Kyphon determined that two defects caused
4 the leaks. First, the seams or “welds” on the saline bag were weak and subject to
5 splitting. Second, the manner in which the bag was sealed to the device with an O-
6 ring allowed saline to leak between the bag and the O-ring. Kyphon had no way of
7 knowing of the leaks prior to the closing of the APA. In fact, Pabban, BMD, BMDI
8 and Herbert took steps to conceal the leaks from Kyphon.

9
10 18. In May 2008 (prior to the August 7 closing of the APA), Pabban
11 provided Kyphon with a copy of Pabban’s Design Failure Mode and Effects Analysis
12 (“DFMEA”) and Process Failure Mode and Effects Analysis (“PFMEA”). These
13 documents, which are standard in the medical device industry, track problems with a
14 device during development, and document how and when the problems were solved.
15 While the documents note pre-closing leaks associated with the O-ring and saline bag,
16 they represent that both issues were corrected and the matters were “closed” on May
17 21, 2008 – one day *before* Kyphon’s first due diligence visit.

18
19 19. After the closing, Kyphon misplaced the disk that contained the Design
20 History File that Pabban provided to Kyphon prior to the closing. Kyphon then asked
21 Pabban provide another copy of the DHF, which Pabban did. That second DHF,
22 however, included a “Performance Qualification Protocol” that sets forth test
23 parameters relating to the detection of saline leaks in the Natrix System. That
24 document is dated August 7, 2008 – the date of the closing. The document shows that
25 Pabban was attempting to correct dangerous saline leaks *on the same day* that
26 Kyphon paid Pabban in excess of \$18 million for a medical device that Pabban
27 represented was market-ready and to be used on patients.
28

1 20. The saline leak posed a number of problems, including the inability to
2 properly sterilize the Natrix System. Not surprisingly, a medical device like the
3 Natrix System must be sterilized before it can be used during an operation. The
4 process used to sterilize the Natrix System is known as “gamma radiation
5 sterilization.” After sterilization, the product should show a “bioburden count” of less
6 than 2000 “colony forming units” or CFU’s.

7
8 21. After the APA closed, the Natrix devices delivered to Kyphon were
9 packaged individually in sealed trays. The outside of each package bore the following
10 label:

11
12 Single use only. Do not reuse or resterilize.

13 Sterile only if pouch is unopened and undamaged.

14
15 In addition, a “Product Information Data Sheet” was inside each sealed package. That
16 document provided, in part, as follows:

17
18 The contents of the inner package (tray) are gamma
19 sterilized. Contents are only sterile if the inner package is
20 not open, damaged, or broken.

21
22 22. Kyphon opened the packages and tested whether the devices had been
23 sterilized properly. Kyphon’s testing showed unacceptably high bioburden counts,
24 which rendered the device unmerchantable. Simply put, an unsterilized Natrix
25 System could not be sold for use during an operation on a patient’s spine.

1 23. Kyphon raised the bioburden issue with Pabban. On September 23,
2 2008, Pabban sent an email to Kyphon in which Pabban admitted that the bioburden
3 problems were caused by the undisclosed saline leaks:
4

5 I also spoke with Fred Weber (President of Sterility Assurance
6 Laboratories) yesterday. I spoke to him about our bioburden issue
7 on the delivery gun. He feels strongly that the saline exposure is
8 the cause of the high bioburden counts.
9

10 24. On September 17, 2008, Kyphon sent an email to Pabban complaining of
11 the defects. Pabban responded with an email on September 18, 2008, in which
12 Pabban admitted that the devices were “unacceptable” and a “disappointment”:
13

14 ... I agree that there has been some quality related issues that are
15 unacceptable, and frankly a disappointment to me.
16

17 25. In October 2008, Kyphon retained its own expert, SteriPro Labs, to
18 perform bioburden testing. SteriPro’s report showed CFU’s that were “too numerous
19 to count,” which means that the device is simply not sterilizable. Such a device
20 presents a danger of serious injury or death and, therefore, cannot be sold.
21

22 26. Prior to the close of the APA, Kyphon reviewed documentation that
23 showed Pabban was using 27.5 kilogray to sterilize the devices, when 25 kilogray
24 should have been sufficient. Kyphon asked Pabban why Pabban was using 27.5
25 kilogray. Pabban responded that it did not know why. After the closing, and after the
26 bioburden problems were discovered by Kyphon, it again raised the issue with
27 Pabban. At that time, Pabban reluctantly acknowledged that Pabban did indeed have
28 pre-closing bioburden problems.

1 27. The defects in the Natrix System made the product dangerous and
2 unmerchantable because they posed a serious and prohibitive risk to patients.
3 Therefore, on October 21, 2008, Kyphon terminated the Supplier Agreement with
4 Syntech. Syntech did not challenge the termination.

5
6 28. Kyphon immediately began the process of correcting the defects. That
7 process included significant research and development efforts, followed by
8 compliance testing and validation. However, that process caused sales of the product
9 to be delayed and Kyphon lost the “first to market” advantage that it sought and for
10 which it paid.

11
12 29. In September 2009, after an eleven month delay caused by the defects
13 described herein, Kyphon launched the Kyphon Cement Delivery System. Because of
14 the delay, Kyphon lost substantial sales and market share, which reduced the value of
15 the Natrix System by an amount in excess of \$40 million.

16
17 30. The APA the parties negotiated provides a remedy for Pabban’s failure to
18 deliver the product it agreed to deliver. By way of example, as set forth more fully
19 below, Pabban represented and warranted to Kyphon and Medtronic, among other
20 things, that the Natrix System was free from significant defects, suitable for its then
21 current use, of merchantable quality, and suitable for its intended and labeled purpose.

22
23 31. In Section 3.9 of the APA, Pabban warranted that:

24
25 Title to and Condition of the Purchased Assets. Seller has full right, title
26 and interest to the tangible Purchased Assets, free and clear of all Liens.

27 The Purchased Assets (other than the Retained Assets or the Business
28 Intellectual Property) include all assets, properties, rights, interests and

1 claims necessary for the conduct of the Business and all assets,
2 properties, rights, interests and claim owned or controlled by Seller or an
3 Affiliate of Seller that relate to the development, manufacture,
4 commercialization or sale of products related to the Business. **The**
5 **Purchased Assets (other than the Retained Assets or the Business**
6 **Intellectual Property) are suitable for the uses for which they are**
7 **presently used by Seller, in normal operating condition and free**
8 **from any significant defects, ordinary wear and tear excepted.** The
9 Purchased Assets include at least those assets listed on Schedule 3.1.1
10 through 3.1.4 (other than the Retained Assets). Except as specifically set
11 forth on Schedule 3.9, all of the Purchased Assets are located at the
12 facilities of Seller.

13
14 (emphasis added).

15
16 32. In Section 3.16 of the APA, Pabban warranted that:

17
18 Manufacturing Processes. Seller has delivered or made available to
19 Kyphon or its Affiliates complete and accurate written documentation of
20 the processes and procedures used or necessary to manufacture the Natrix
21 System as it is currently conducted (the “Manufacturing
22 Documentation”). **To Seller’s Knowledge, the Natrix System, as**
23 **presently designed and configured, and, when manufactured in**
24 **accordance with the Manufacturing Documentation, will materially**
25 **conform to the specifications established therefor and to Seller’s**
26 **Knowledge will be (a) of merchantable quality; (b) free from defects**
27 **in design, material and workmanship; and (c) suitable for their**
28 **intended and labeled purpose.** The Business Intellectual Property

1 includes all the Manufacturing Documentation and all processes,
2 methods, techniques, procedures, trade secrets and know how included
3 therein.

4
5 (emphasis added).

6
7 33. Section 7.1 of the APA mandates that Pabban indemnify Kyphon for all
8 damages, including attorneys' fees, that result from Pabban's breach of the APA. The
9 APA provides:

10
11 [Pabban shall] indemnify, defend and hold harmless [Kyphon]. . . from
12 and against and in respect of any and all paid or incurred losses,
13 damages, liabilities, assessments, interest and penalties, costs and
14 expenses (including, without limitation, reasonable legal fees and
15 disbursements incurred in connection therewith and in seeking
16 indemnification therefore, and any amount or expenses paid or incurred
17 in connection with any action, suit, proceeding, claim, appeal, demand,
18 assessment or judgment), whether or not involving a third party claim,
19 (collectively "Indemnifiable Losses") directly or indirectly resulting
20 from, arising out of, or imposed upon or incurred by any person to be
21 indemnified hereunder by reason of . . . any breach of any representation
22 or warranty of [Pabban].
23

24 34. In addition, the APA grants Kyphon the right to withhold payments to
25 Pabban based on Indemnifiable Losses. In particular, Section 7.3 of the APA
26 provides, in pertinent part, that "Kyphon shall have the right to set-off any claims for
27 Indemnifiable Losses . . . against any payments due and owing to Seller . . . and not
28 yet paid."

1 35. Pabban, BMD, BMDI, and Herbert were aware of the defects, and hid
2 them from Kyphon.

3
4 36. The Natrix System was not suitable for the uses for which it was used by
5 Pabban at the time of the closing.

6
7 37. The Natrix System was not in normal operating condition at the time of
8 closing of the APA.

9
10 38. The Natrix System was not free from significant defects at the time of the
11 closing of the APA.

12
13 39. At the time of the closing of the APA, the Natrix System, as it was then
14 designed and configured, and, when manufactured in accordance with the
15 Manufacturing Documentation, did not materially conform to the specifications
16 established therefore.

17
18 40. At the time of the closing of the APA, the Natrix System was not of
19 merchantable quality.

20
21 41. At the time of the closing of the APA, the Natrix System was not free
22 from defects in design, material and workmanship.

23
24 42. At the time of the closing of the APA, the Natrix System was not suitable
25 for its intended and labeled purpose.

26
27 43. Pursuant to its rights under the APA, Kyphon justifiably withheld
28 milestone payments that may have been otherwise due under the APA.

CLAIM I
BREACH OF CONTRACT
(AGAINST PABBAN)

44. The allegations contained in paragraphs 1-43 of this counterclaim are adopted and incorporated herein by reference as if fully set forth herein.

45. Pabban breached the APA.

46. As a result of Pabban's breach, Kyphon has been damaged in an amount exceeding \$75,000 exclusive of interest and costs, to be determined at trial.

47. As a result of Pabban's breach, Kyphon is entitled to recover its costs, disbursements, and attorneys' fees incurred in this matter pursuant to Section 7.1 of the APA.

CLAIM II
BREACH OF THE DUTY OF GOOD FAITH AND FAIR DEALING
(AGAINST PABBAN)

48. The allegations contained in paragraphs 1-43 of this counterclaim are adopted and incorporated herein by reference as if fully set forth herein.

49. The APA is governed by Delaware law. Under Delaware law, an obligation of good faith and fair dealing is implied into the APA by law. Therefore, pursuant to the APA, Pabban had an obligation to deal with Kyphon fairly and in good faith.

50. Pabban breached its obligation to Kyphon to act fairly and in good faith.

51. As a result of Pabban's breach of its duty of good faith and fair dealing, Kyphon has been damaged in an amount exceeding \$75,000 exclusive of interest and costs, to be determined at trial.

- 1 • The Natrix System, as designed and configured at the time of
- 2 closing of the APA, when manufactured in accordance with the
- 3 Manufacturing Documentation, did not materially conform to the
- 4 specifications established therefore;
- 5
- 6 • At the time of the closing of the APA, the Natrix System was not
- 7 of merchantable quality;
- 8
- 9 • At the time of the closing of the APA, the Natrix System was not
- 10 free from defects in design, material, or workmanship;
- 11
- 12 • At the time of the closing of the APA, the Natrix System was not
- 13 suitable for its intended and labeled purpose.
- 14

15 56. At the time Pabban, BMD, BMDI, and Herbert made the representations
16 set forth above, they knew those representations were false.

17

18 57. Pabban, BMD, BMDI, and Herbert made the representations with the
19 intent to induce Kyphon to purchase the Natrix System.

20

21 58. Kyphon relied on Pabban, BMD, BMDI, and Herbert's representations,
22 and Kyphon was justified in relying on Pabban's representations.

23

24 59. As a result of Pabban's misrepresentations, Kyphon has been damaged in
25 an amount exceeding \$75,000 exclusive of interest and costs, to be determined at trial.

CLAIM IV
DECLARATORY RELIEF
(AGAINST PABBAN)

60. Medtronic adopts and incorporates by reference as if fully set forth herein paragraphs 1-43 of this counterclaim.

61. An actual controversy has arisen and now exists between Medtronic and Pabban concerning their respective rights and obligations under the APA.

62. Medtronic contends that it has no obligations to Pabban whatsoever, including any purported obligation to guaranty any alleged obligation of Kyphon.

63. Pabban disputes this contention and contends that Medtronic is obligated to guaranty the purported obligation of Kyphon to make milestone and royalty payments for sales of the Natrix System.

64. A judicial declaration is necessary and appropriate at this time under the circumstances, in order that Medtronic may ascertain its rights and duties under the APA. Declaratory relief would resolve Pabban's allegation that Kyphon breached the APA by not making certain milestone and royalty payments as set forth in the APA.

WHEREFORE, Kyphon and Medtronic demand judgment against Pabban, BMD, BMDI, and Herbert as follows:

1. Money damages in an amount exceeding \$75,000, the exact amount to be determined at trial:

a. Against Pabban for breach of the APA and for fraud; and

b. Against BMD, BMDI and/or Herbert, for fraud;

2. Awarding Kyphon and Medtronic their costs and attorneys' fees incurred herein;

3. A determination that Medtronic has no obligation to Pabban under the APA, including but not limited to any purported obligation to guaranty the payment of milestones and royalties;

4. Punitive damages in an amount to be proven at trial; and

5. For such other and further relief as the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Kyphon Sàrl and Medtronic, Inc. hereby demand a jury trial.

DATED: June 16, 2011.

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